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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/510,959 | 08/10/2005 | David Lovejoy | 2223-189 | 2108 |
| 27155 7590 10/04/2010 | | | | |
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| EXAMINER | | | | |
| MACFARLANE, STACEY NEE | | | | |
| ART UNIT | | PAPER NUMBER | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/510,959

Applicant(s)

LOVEJOY ET AL.

Examiner

STACEY MACFARLANE

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-10 and 12-52 is/are pending in the application.
- 4a) Of the above claim(s) 12-33 and 35-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-10 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 26, 2010 has been entered.

Response to Amendment

2. Claims 8 and 9 have been amended as requested in the amendment filed on May 26, 2010. Following the amendment, claims 8-10, 12-52 are pending in the instant application.

Claims 10, 12-33 and 35-52 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper filed on April 29, 2008.

Claims 8-10 and 34 are under examination in the instant office action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 8-10 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claim 8 is indefinite in that it recites "consists essentially of" the amino acid sequence as shown in SEQ ID NO: 69. The term "consists essentially of", while well-defined for compositions, has no legal definition as applied to single molecules. For amino acid sequences, for example, the person of ordinary skill in the art would not know whether the claims allow for internal variation, or alternatively allow for the addition of sequences to the ends so long as the "essential" function is not affected adversely. Furthermore, in the instant case, there is no clear function defined. Thus, a skilled artisan would not know what "essential" function is required by the claim.
6. Claim 8 is further indefinite in that it recites a "homolog thereof", which is not defined in the specification, and is therefore indefinite.
7. Claims 9, 10 and 34 are indefinite for depending from an indefinite claim.
8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
9. Claims 8-10 and 34 stand as rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for reasons of record in the previous Office action.

10. On page 9 of Remarks filed May 25, 2010, Applicant states the following in traverse:

"the Application is replete with support of homologs. The Examiner has not objected to this term. With respect to the terms "analogs" and "derivatives", they are defined in paragraphs [102] and [103] respectively and sufficiently provide structural definitions however, Applicant has mended claim 8 without prejudice to the doctrine of equivalents and pursuing any such subject matter in this or a divisional, continuation, or continuation-in-part or other application by removing reference to "analog" and "derivative" from claim 8.. Last, Application submits that this is not the situation where only one sequence has been provided. Applicant has provided many examples within this novel peptide family as evidenced by the sequence listing submitted with the application and the Examples. It is submitted that the Applicant has demonstrated possession of the genus of molecules encompassed by the claims."

While Figures 7B specifically lists homologs that have 60 to 97% homology to SEQ ID NO: 69, Examiner maintains that there is inadequate written description for those homologs that fulfill the requirements of the instant claims: namely, "38 to 41 amino acids" "consisting essentially of SEQ ID NO: 69", and those that have the requisite biological or "anxiogenic" activity (claim 10). Thus, the claims are drawn to a genus of molecules for which there is no defined structure, and which are merely described by their activity. As stated above in section 4 of the Office action, one of ordinary skill is not even sure what that activity is required. The specification specifically says that it can be immunologic activity (paragraph [0138]). Additionally, the claims encompass "homologs" for which there is no explicit definition within the specification. Thus, there is not even identification of any particular portion of "the at least 38 amino acids" that must be conserved among homologs or required in order to maintain the claimed activity. For example, the specification discloses a drosophila homolog that is only 60% homologous, shares 12 common amino acids with the human

sequence; however, the specification provides no information regarding this peptide's biological activity. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus and Applicant has not demonstrated possession of the genus of molecules encompassed by the claims. Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 8, 10 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Rubin et al., Developmental Biology 216:196-209, 1999.

13. Claims 8 and 34 are drawn to isolated peptides consisting essentially of an amino acid sequence shown in SEQ ID NO: 69 or homolog thereof; and pharmaceutical compositions comprising said peptide. Claim 10 recites the peptide of claim 8 wherein the peptide has “anxiogenic activity”. This recitation fails to further structurally limit the parent claim, and since no activity is clearly defined within the specification, this limitation appears to be drawn to an inherent feature/property of the peptide claimed.

14. As stated above, the specification lacks an explicit definition for “homolog” and it is unclear what “consisting essentially of” means for a peptide for which there is no clearly defined function. The specification discloses that the activity of the peptide

includes immunological activity. Therefore, the claim has been interpreted to read upon homologs of SEQ ID NO: 69 and pharmaceutical compositions thereof used to produce antibodies.

15. The Ruben et al., prior art teaches an affinity purified *Drosophila* teneurin-2 peptide (TN/ten-2) that is used to produce an immunological response in rabbits (page 197). Therefore the peptide of the instant claims fails to distinguish over that disclosed by the prior art.

Conclusion

16. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STACEY MACFARLANE whose telephone number is (571)270-3057. The examiner can normally be reached on M-R 5:45 to 3:30, TELEWORK-Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stacey MacFarlane
Examiner
Art Unit 1649

/Lorraine Spector/
Primary Examiner, Art Unit 1647